REMARKS

Claims 1, 4, 52, 64-69, and 85-113 are pending in the application. Claims 85-90 have been amended. Support for the amendments can be found in the specification at, e.g., page 3, line 25, to page 8, line 6. No new matter has been added.

Priority Date of Claims

In the "Remarks" section of the response to the prior Office Action, applicants noted that all of the pending claims are entitled to at least the priority date of prior International Application Number PCT/US98/01499, filed January 22, 1998 ("the '499 application"). However, the present Office Action asserts that the claims are entitled to only the priority date U.S. Application No. 09/266,463, filed March 11, 1999 ("the '463 application"). In particular, the Office Action asserts (at page 2) that all of the applications in the priority chain prior to the '463 application "consider use of lipids as stabilizers present in excipient formulations" but "do not contemplate a microparticle comprising a lipid."

Applicants respectfully contest the Office's position with respect to the priority date of the pending claims.

The introductory paragraph beginning at page 2, line 4 of the '499 application states that "[i]n general, the invention features a preparation of microparticles (also called microspheres), each of which includes a polymeric matrix and a nucleic acid expression vector." The subsequent paragraph, at page 2, lines 23-33 of the '499 application, reads as follows:

> The preparation can also include a stabilizer compound (e.g., a carbohydrate, a cationic compound, or a DNA-condensing agent). A stabilizer compound is a compound that acts to protect the nucleic acid (e.g., to keep it supercoiled) at any time during the production of microparticles. Examples of stabilizer compounds include dextrose, sucrose, dextran, polyvinyl alcohol, cyclodextrin, dextran sulfate, cationic peptides, and lipids such as hexadecyltrimethylammonium bromide. The stabilizer compound can remain associated with the DNA after a later release from the polymeric matrix. (emphasis added)

The foregoing passage of the '499 application provides clear support for a preparation of microparticles that contains a stabilizer compound such as a lipid.

In addition, page 13, lines 11-21 of the '499 application states:

> In another embodiment, the invention features a preparation of microparticles, each of which includes a polymeric matrix, a stabilizing compound, and a nucleic acid expression vector. The polymeric matrix includes one or more synthetic polymers having a solubility in water of less than about 1 mg/l; in the present context, synthetic is defined as non-naturally occurring. At least 90% of the microparticles have a diameter less than about 100 microns. The nucleic acid is either RNA, at least 50% (and preferably at least 70% or even 80%) of which is in the form of closed circles. (emphasis added)

The foregoing passage of the '499 application provides further unambiguous disclosure of a microparticle containing a stabilizer compound (together with a polymeric matrix and a nucleic acid expression vector). In addition to the paragraph at page 2, lines 23-33 reproduced above, further description of lipids as exemplary stabilizer compounds is provided at page 23, lines 16-20 of the '499 application.

> Stabilizers such as charged lipids (e.g., CTAB), cationic peptides, or dendrimers (J. Controlled Release, 39:357, 1996) can condense or precipitate the DNA. Moreover, stabilizers can have an effect on the physical nature of the particles formed during the encapsulation procedure. (emphasis added)

The remarks above establish that the '499 application clearly discloses microparticles comprising a stabilizer compound and that a lipid can be used as the stabilizer compound.

In view of the foregoing remarks, applicants respectfully submit that all of the pending claims are entitled to at least the priority date of priority International Application Number PCT/US98/01499, filed January 22, 1998.

Claim Objections

At pages 3-4 of the Office Action, claims 85-90 were objected to because of several informalities. Claims 85-90 have been amended, thereby obviating the present objection.

35 U.S.C. § 103(a)

At pages 4-7 of the Office Action, claims 1, 4, 52, 63-69, and 85-113 were finally rejected as allegedly unpatentable over Hedley et al., U.S. Patent No. 5,783,567 ("Hedley") in view of Lambert et al. (1998) Biochimie 80:969-76 ("Lambert") or Balland (1996) NATO ASI Series 290:131-42 in view of Knepp et al., U.S. Patent No. 6,264,990 ("Knepp").

At least the cited references Lambert and Knepp do not constitute prior art against the pending claims. Lambert was published in December 1998 and Knepp is entitled to a §102(e) date of December 14, 1999. As noted above, all of the pending claims are entitled to at least the January 22, 1998 priority date of International Application Number PCT/US98/01499.

In view of the foregoing remarks, applicants request that the Examiner withdraw the rejection.

At pages 7-9 of the Office Action, claims 1, 4, 52, 63-69, and 85, 86, and 88-113 were finally rejected as allegedly unpatentable over Papahadjopoulos et al., U.S. Patent No. 6,210,707 ("Papahadjopoulos") in view of Cleek et al. (1997) J. Biomed. Materials Res. 35:525-30 ("Cleek") as evidenced by Manoharan et al., U.S. Published Application No. 2005/0153337 ("Manoharan").

The application that gave rise to the Papahadjopoulos patent was filed on May 12, 1998, which is after the priority date of the pending claims. Papahadjopoulos would only constitute prior art under §102(e) if the Examiner were to identify relevant passages in one or more Papahadjopoulos priority patent applications filed before the priority date of the claims. The Office Action contains no suggestion that any of the Papahadjopoulos priority applications are relevant to the claimed invention.

In view of the foregoing remarks, applicants request that the Examiner withdraw the rejection.

CONCLUSION

Applicants submit that all grounds for rejection have been overcome and that all claims are in condition for allowance, which action is requested.

Enclosed is a Petition for Extension of Time. The extension of time fee is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any deficiencies or credit any overpayment to deposit account 06-1050, referencing Attorney Docket No. 08190-014002.

Respectfully submitted,

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